REMARKS

Applicants respectfully request reconsideration and reexamination of the present application in light of the foregoing amendments and following remarks. Amendments are made without disclaimer of any subject matter, and Applicants expressly reserve the right to claim such subject matter in a subsequently filed continuing application.

1. Status of the Claims

Claims 1-16 are pending. Claims 1-14 stand rejected. The Office Action Summary indicates that claims 15-16 are withdrawn from consideration. The Office indicates at page 2 of the Office Action, however, that claims 14-15 are withdrawn. Applicants assume that the Office meant claims 15-16 are withdrawn, because these claims are directed to a method of using the compounds of claims 1 and 2. Applicants request clarification in the Office's next communication.

2. Support for the Amendments

The amendments are supported throughout the application as filed. Claims 1-2 recite an *isolated* flavone C-glycoside derivative of formula (1) or (2) or a salt thereof *purified to at least about 0.001 weight % dry solids*. Support for isolation and purification of the compounds of formula (1) and (2), or a salt thereof from a tea extract, is found throughout the specification, for example, at page 2, line 24 ("isolated"), and page 14, line 7, through page 17, line 5 (purification and concentration from a tea extract). The specification, for example, provides a range of concentration of 0.001 – 100 weight % at which the compounds may be present in a composition, which also provides a measure of the degree of purification of the compounds. *See* Specification, page 12, line 27, *et seq.*; page 13, lines 24-27.

Methods and compositions in new claims 17-28 that recite *at least about 0.001 weight % dry solids* of one of the flavone C-glycoside derivatives or salt thereof according to claims 1 and 2 are supported throughout the specification, for example, at page 13, lines 24-27. Additional support for new claims 17-28 can be found, for example, in claims 3-14.

For all these reasons, the amendments do not add subject matter that is unsupported in the specification as filed. Accordingly, no prohibited new matter is introduced by the entry of the amendments.

3. Acknowledgement of Information Disclosure Statements

Applicants note with appreciation the acknowledgement of the Information Disclosure Statement filed September 21, 2007.

4. Election/Restriction and Request for Rejoinder

Applicants request timely rejoinder of claims 15-16 are eligible for rejoinder after the allowance of the claims being examined, because claims 15-16 are directed to processes to use the claimed compounds. *See* M.P.E.P. § 821.04.

5. Rejection under 35 U.S.C. § 101

Claims 1-2 are rejected under 35 U.S.C. § 101 as being allegedly directed to non-statutory subject matter. Claims 1-2 are amended to recite that the compounds are "isolated," as the Examiner suggests. Further, the claims are amended to recite that the compounds are purified to at least about 0.001 weight % dry solids. The claims thus are directed to statutory subject matter. The rejection accordingly should be withdrawn.

6. Rejection Under 35 U.S.C. § 102(b)

The Office maintains the rejection of claims 1-7, 10-12, and 14 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,409,692 ("Nakahara"). Applicants traverse the rejection.

[A]

Applicants traverse for the following reasons with respect to claims 1 and 2 and new claims 17-28. Claims 1 and 2 are directed to a flavone C-glycoside derivative of formula (1) or (2) purified to at least about 0.001 weight % dry solids or salt thereof. Claims 3-14 are directed to compositions and methods for preparing compositions containing a therapeutically effective amount of one of the flavone C-glycoside derivative according to formulas (1) or (2) or salt thereof. New claims 15-28 are directed to compositions and methods for preparing compositions containing at least about 0.001 weight % dry solids of one of the flavone C-glycoside derivative according to formulas (1) or (2) or salt thereof.

The present specification discloses an example of the purification of a compound of formulas (1) and (2). In this example, 5000 g of oolong tea leaves are used to prepare an aqueous extract, which is then subjected to further purification with a DIAION HP-21

column. The non-adsorbed fraction from the DIAION HP-21 column is collected and fractionated with ethanol. *See* Specification, page 14, lines 5-17. The 517 g of material from the ethanol fractionation is further purified to produce 980 μg of the purified, concentrated compound of formula (1) (*see* Specification, page 14, line 18, through page 15, line 9) or 147 μg of the purified compound of formula (2) (*see* Specification, page 16, line 4, through page 17, line 5).

It is reasonable to assume that the compound of formula (1) is present at a concentration no higher than roughly 0.0002 weight % in the aqueous tea extract (i.e., 980 μg compound of formula (1) in 517 g of ethanol fractionated aqueous tea extract). Applicants assume for simplicity that the 517 g of ethanol fractionated extract contains all of the solid matter of the tea extract. The amount of the compound of formula (1) in tea extract presumably is lower than 0.0002 weight %, because the ethanol fractionation further purifies the compound of formula (1). Further, it is reasonable to assume that the compound of formula (2) is present at a comparable, although lower, concentration than the compound of formula (1) (i.e., 147 μg/517 g).

Nakahara discloses the following. Nakahara prepares 16.5 g of an extract from 100 g of oolong tea leaves (*see* Example 1, col. 5, lines 39-53; *see also* col. 3, lines 38-49). Nakahara runs 15 g of the oolong tea extract over a DIAION HP-21 column and collects 6.4 g from the non-adsorbed fraction (*see* Example 3, col. 5, lines 55-68; *see also* col. 3, lines 50-65). Nakahara prepares various compositions including a chewing gum that comprises 0.01 weight % of the non-adsorbed fraction of oolong tea extract as prepared in Example 3 (*see* Example 15; *see also* Examples 5-9; col. 4, lines 6-15). Throughout the following discussion, Applicants assume for the sake of argument that the compounds of formula (1) and (2) are present in the oolong tea leaves and extracts disclosed by Nakahara. However, there is no evidence that this is true from the disclosure of Nakahara.

Nakahara does not teach greater purification of an oolong tea extract than the collection of 6.4 g of material from the non-adsorbed fraction of a DIAION HP-21 column from 15 g of an aqueous oolong tea extract (Example 3). So the compounds of formula (1) and (2) cannot be more than about three-fold purified over their concentration in an aqueous tea extract in Nakahara (i.e., 6.4 g/15 g). As set forth above, the compound of formula (1) cannot be present at a concentration higher than roughly 0.0002 weight % in an aqueous tea extract. This means that the compound of formula (1) presumably is present at a

concentration at best no higher than about ***0.0006 weight %*** in the three-fold purified extract of Example 3 of Nakahara. This concentration is far lower than the recited concentration of at least about 0.001 weight % of dry solids.

Nakahara also teaches a chewing gum composition containing 0.01 weight % of the extract of Example 3 (Example 15) or tooth paste composition containing 0.05 weight % of an aqueous oolong tea extract (Example 5), or a sugar composition containing about 0.43 weight % of an oolong tea extract (Example 8).

Nakahara's compositions reasonably must contain the compound of formula (1) at a concentration much lower than the recited 0.001 weight % dry solids. Consider Nakahara's chewing gum composition, for example. Assuming the compound of formula (1) were present at 0.0006 weight % in Nakahara's fractionated oolong tea extract, the compound of formula (1) would be present at roughly ***0.000006 weight %*** in Nakahara's composition, because the oolong tea extract constitutes only 0.01 weight % of Nakahara's composition (0.01 weight % extract in the composition × 0.0006 weight % of the compound in the extract). The concentration of 0.000006 weight % is about ***three orders of magnitude lower*** than the recited concentration of the compound of formula (1) in the claimed compositions. That is, this concentration is not at least about 0.001 weight % dry solids, as recited.

Nakahara accordingly does not explicitly or inherently teach all the elements of the claims. Because Nakahara does not teach all the elements of the claims, it does not anticipate the claims. The rejection of claims 1-7, 10-12, and 14 over Nakahara accordingly should be withdrawn.

[B]

Applicants traverse for the following reasons with respect to claims 3-14. The Office cites *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977) for the proposition that the Office need only establish a reason to believe that an element is in fact inherent in the prior art. *Best*, however, does not excuse the Office from further establishing that the allegedly inherent property ***necessarily*** is found in the cited art. *See, e.g., In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981) ("Inherency, however, may not be established by probabilities or possibilities."). Put another way, while the Office may make a reasonable case that a property is necessarily inherent in the prior art, the Office may not find that the property reasonably ***may*** be inherent in the prior art.

In the present case, the Office alleges that Nakahara's disclosed oolong tea extract may be the inherent property of containing the recited compounds in claims 1 or 2. The Office, however, provides no evidence that the oolong tea extract of Nakahara ***necessarily*** contains a therapeutically effective amount of these compounds. The Office assumes that the chemical contents of oolong tea extract do not vary with geographical area, season, or manufacturing process. In this context, Applicants make of record Ikegaya, FOOD SCIENCE SERIES: TEA SCIENCE, K. Muramatsu, ed., Asakura Shoten, Tokyo, Japan, pp. 86-94 (1991) ("Ikegaya") and an English translation thereof. Ikegaya discloses throughout that the chemical composition of tea leaves may vary, depending on the tea type, grade of a particular tea type, time of harvest, time required for commercial processing, and hardness of the leaves. *See, e.g.*, Ikegaya, Table 4.1; page 2, ¶1[1]; page 4, ¶2; and page 7, ¶1, respectively. Even when all these factors are constant, some tea contents, e.g., magnesium and aluminum, may vary widely. *See* Ikegaya, page 7, ¶2. Certainly, once an active compound is identified, its quantity in tea leaves can be controlled. Until then, however, the contents of a tea leaf extract may vary. For this reason, the Office produces insufficient evidence that the oolong tea extract of Nakahara ***necessarily*** contains a therapeutically effective amount of these compounds. Because the Examiner does not properly shoulder his burden of evidence, the rejection should be withdrawn.

7. Rejection under 35 U.S.C. § 102(e)

The Office maintains the rejection of claims 1-14 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Published Application No. 2002/0136753 A1 ("Uehara"). Applicants traverse the rejection.

[A]

Applicants traverse for the following reasons with respect to claims 1 and 2 and new claims 17-28. Uehara teaches compositions comprising as much as 40 weight % of an aqueous oolong tea extract. *See* Uehara, ¶¶ 17, 21, 30. For the reasons set forth above, it is reasonable to assume that the compound of formula (1) cannot be present at a concentration higher than roughly 0.0002 weight % in an aqueous oolong tea extract. It also is reasonable to assume that the compound of formula (2) is present at roughly the same concentration. *Id.*

[1] Page numbers refer to the translation of Ikegaya.

Given these assumptions, Uehara's composition having 40 weight % of an oolong tea extract would contain roughly ***0.00008 weight %*** of the compound of formula (1) (40 weight % extract in the composition × 0.0002 weight % of the compound in the extract). This concentration, is about ***three orders of magnitude lower*** than the recited concentration of the compound of formula (1) in the claimed compositions. That is, this concentration is not at least about 0.001 weight % dry solids, as recited. Thus, the reference fails to teach or suggest the limitations of claims 1, 2, and 17-28.

[B]

Applicants traverse for the following reasons with respect to claims 3-14. For the reasons stated above, the Office produces insufficient evidence that the oolong tea extract of Uehara ***necessarily*** contains a therapeutically effective amount of the compounds recited in claims 1 or 2. Because the Examiner does not properly shoulder his burden of evidence, the rejection should be withdrawn.

Accordingly, Uehara does not explicitly or inherently teach all the elements of the claims. Because Uehara does not teach all the elements of the claims, it does not anticipate the claims. The rejection of claims 1-14 over Uehara accordingly should be withdrawn.

CONCLUSION

In view of the above arguments and amendments to the claims, Applicants respectfully assert that the claims are condition for allowance and respectfully request a Notice of Allowance.

Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573 accordingly.

Respectfully submitted,

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